

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s):	Joseph P. ORBAN III et al.	Examiner:	Julian W. Woo
Serial No.:	10/516,435	Art Unit:	3731
Filed:	November 30, 2004	Dated:	July 11, 2008
For:	<b>ANNULAR SUPPORT STRUCTURES</b>		

Mail Stop Appeal Brief – Patents  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 2213-1450

*Filed Via EFS-Web*

**APPEAL BRIEF**

Sir:

This Appeal Brief is submitted in response to the Final Rejection mailed December 27, 2007 in connection with the above-identified patent application.

**I. REAL PARTY IN INTEREST**

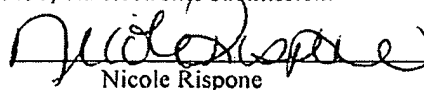
The real party in interest for this application is Tyco Healthcare Group LP (d/b/a Covidien), having a principal office at 60 Middletown Avenue, North Haven, CT 06473.

---

**CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. §1.8(a)**

I hereby certify that this correspondence is being transmitted on the date below with the United States Patent and Trademark Office, PO Box 1450, Alexandria, VA 22313-1450, via electronic submission.

Dated: July 11, 2008

  
Nicole Rispon

## **II. RELATED APPEAL AND INTERFERENCES**

There are no other related prior or pending appeals or interferences for this application.

## **III. STATUS OF CLAIMS**

The status of the claims of this application is as follows:

- A) Claims 1-24 are pending;
- B) Claims 1-15, 23 and 24 stand rejected and are being appealed; and
- C) Claims 16-22 have been withdrawn from consideration.

## **IV. STATUS OF AMENDMENTS**

A response to the Final Rejection was filed on March 24, 2008 requesting reconsideration and allowance of the above-identified application. In an Advisory Action mailed on April 8, 2008, the Examiner stated that the request has been considered, but that the above-identified application was not in condition for allowance.

## **V. SUMMARY OF CLAIMED SUBJECT MATTER**

The above-identified application relates to a support structure for use in conjunction with a circular endoscopic stapling instrument. The endoscopic stapling instrument 10 having a staple cartridge assembly 14 and an anvil assembly 16. (*see page 7, lines 31-34; see FIG. 1*). The staple cartridge assembly 14 having at least one annular arrangement of staple slots 18 and staples 20 positioned in the slots 18. (*see page 8, lines 1-2; see FIGS. 1-2*). The support structure comprising an annular ring 402 and a wound closure material "W". (*see page 13, lines 3-13; see FIG. 10*). The

annular ring 402 configured and adapted to substantially overlies the at least one annular arrangement of staples 20 of the staple cartridge assembly 14. (*see* page 7, line 34; *see* page 8, lines 1-2; *see* FIGS. 1-2). The annular ring 402 including an outer annular wall 404, an inner annular wall 406, an upper wall 408 and a lower wall 410. (*see* page 13, lines 3-4; *see* FIGS. 9-10). The outer annular wall 404 having a diameter. The inner annular wall 406 spaced a radial distance inward of the outer annular wall 404 and defining a space 416. (*see* page 13, lines 3-6; *see* FIGS. 9-10). The upper wall 408 interconnecting the outer annular wall 404 and the inner annular wall 406. (*see* page 13, lines 3-5; *see* FIGS. 9-10). The lower wall 410 spaced a distance from the upper wall 408 and interconnecting the outer annular wall 404 and the inner annular wall 406. (*see* page 13, lines 3-5; *see* FIGS. 9-10). The outer annular wall 404, the inner annular wall 406 and the upper and lower walls 408 and 410 defining an interior reservoir 412. (*see* page 13, lines 6-7; *see* FIGS. 9-10). The wound closure material "W" retained in the reservoir 412 and dispensable therefrom. (*see* page 13, lines 11-13; *see* FIGS. 9-10).

#### **VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

Appellants request review of the following outstanding rejections:

- A) The rejection of claims 1, 3, 6-10, 12, and 13 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,796,603 to Dahlke et al (hereinafter "Dahlke");
- B) The rejection of claims 1, 10, 11, 14, and 15 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,712,853 to Kuslich (hereinafter "Kuslich");
- C) The rejection of claim 1 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 3,022,810 to Lambe (hereinafter "Lambe");

- D) The rejection of claim 23 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,909,972 to Britz (hereinafter “Britz”);
- E) The rejection of claim 2 under 35 U.S.C. §103(a) as being anticipated by Dahlke;
- F) The rejection of claims 1 and 4 under 35 U.S.C. §103(a) as being unpatentable over Britz in view of U.S. Patent No. 3,022,810 to Lambe;
- G) The rejection of claim 5 under 35 U.S.C. §103(a) as being unpatentable over Britz in view of Lambe and further in view of U.S. Patent No. 4,231,407 to James (hereinafter “James”); and
- H) The rejection of claim 24 under 35 U.S.C. §103(a) as being unpatentable over Britz in view of James.

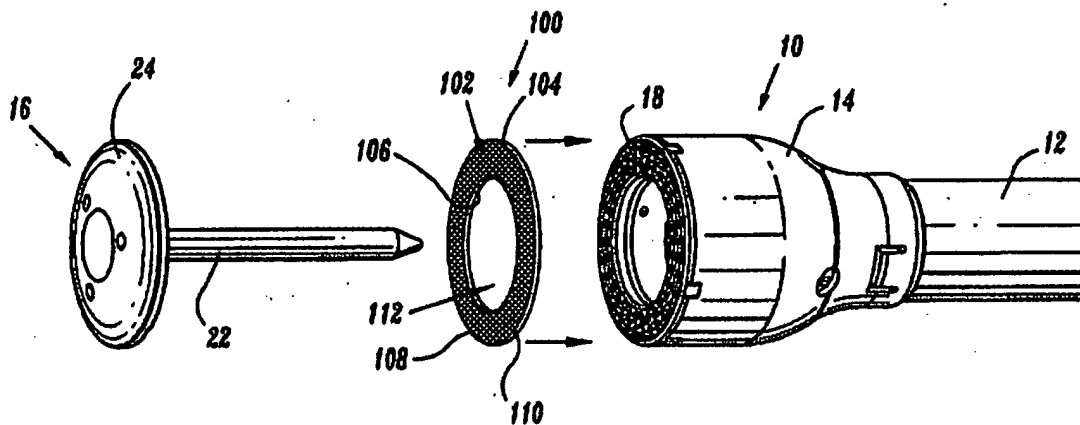
## **VII. ARGUMENTS**

### **A) The rejection of claims 1, 3, 6-10, 12, and 13 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,796,603 to Dahlke et al**

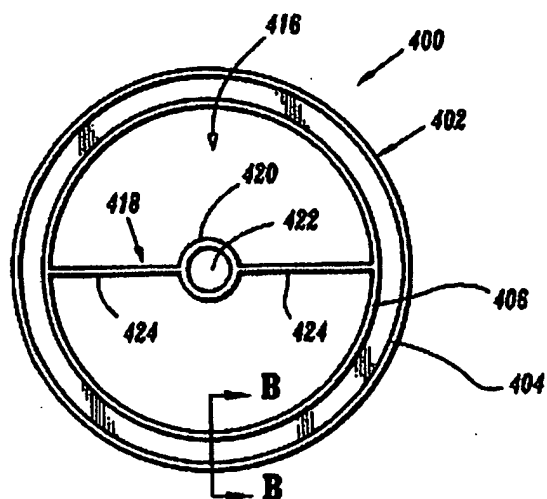
Claims 1, 3, 6-10, 12, and 13 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,796,603 to Dahlke et al. Appellants respectfully submit that claim 1 is allowable under 35 U.S.C. §102(b) over Dahlke because Dahlke fails to disclose each and every feature of claim 1. Accordingly, Appellants respectfully request withdrawal of the rejection to claim 1.

According to §2131 of the MPEP, to anticipate a claim, the reference must disclose every element of the claim, “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.”

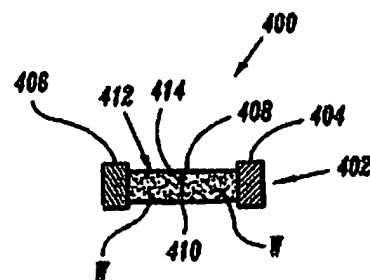
FIG. 1 shows a support structure including an annular ring configured and adapted to substantially overlies at least one annular arrangement of staples. FIGS. 9 and 10 show an embodiment in which the annular ring defines a reservoir, and a wound closure material retained in the reservoir and releasable therefrom. Independent claim 1 recites a support structure including, *inter alia*, an annular ring configured and adapted to substantially overlies the at least one annular arrangement of staples of the staple cartridge assembly, the annular ring defining a reservoir, and a wound closure material retained in the reservoir and releasable therefrom.



**FIG. 1**

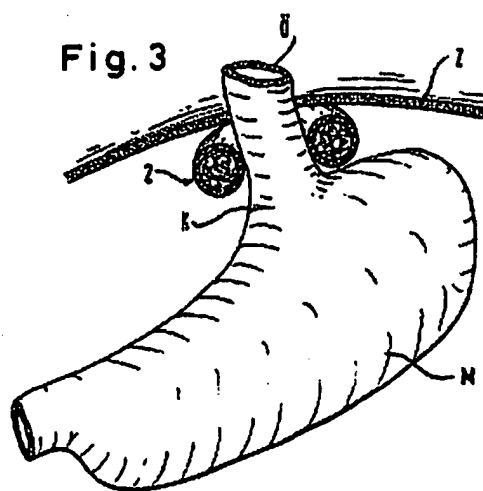


**FIG. 9**



**FIG. 10**

In contrast, Dahlke discloses a hose-like implant or pad hose 2 which is placed in an annular manner around the esophagus O above stomach M, as shown below in Fig. 3. Dahlke further discloses the pad hose 2 comprises a porous sheet-like material and is placed in a collar-like manner around the distal esophagus and sewn together at the overlapping ends. (See col. 3, lines 40-42 and col. 4, lines 1-4).



Dahlke discloses that the filling of the implant is penetrated by the ingrowth of tissue. The outer sleeve is knitted or woven from fibres of a resorbable material and the filling is made of filaments that allow penetration of tissue. Col. 2, lines 60 through 66. However, allowing the penetration of tissue is the opposite of dispensing material, as required by claim 1.

The implant hose 2 disclosed by Dahlke is not an annular ring configured to substantially overlie an annular arrangement of staples of the staple cartridge assembly, as recited in claim 1.

Claim 1 is directed to a support structure. In direct contrast, implant hose 2 of Dahlke is placed around the esophagus of the patient to constrict the esophagus, which is the opposite of supporting the esophagus in an open position. Dahlke discloses that the implant is for the treatment of hernias and is placed around the gastro-esophageal junction. Col. 1, lines 21 through 42.

Accordingly, in view of the foregoing amendments and remarks, Appellants respectfully submit that Dahlke fails to disclose or even suggest each and every element recited in claim 1, because Dahlke does not disclose or suggest a support structure including, *inter alia*, an annular ring configured and adapted to substantially overlie the at least one annular arrangement of staples of the staple cartridge assembly, the annular ring defining a reservoir, and a wound closure material retained in the reservoir and dispensable therefrom, as recited in claim 1.

In view of the arguments presented above, Appellants respectfully submit that claim 1 is allowable under 35 U.S.C. § 102(b) over Dahlke because Dahlke fails to disclose each and every element of claim 1.

Since claims 3, 6-10, 12, and 13 depend, directly or indirectly, from independent claim 1, and contain all of the features of claim 1, for the reasons presented above regarding the patentability of claim 1, Appellants respectfully submit that claims 3, 6-10, 12, and 13 are also patentable over Dahlke.

**B) The rejection of claims 1, 10, 11, 14, and 15 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,712,853 to Kuslich**

---

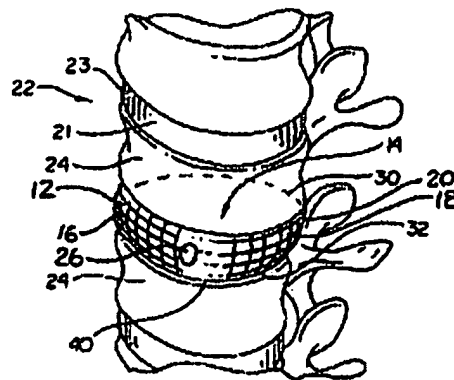
Claims 1, 10, 11, 14, and 15 were rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,712,853 to Kuslich. Appellants respectfully submit that claim 1 is allowable under 35 U.S.C. § 102(e) over Kuslich because Kuslich fails to disclose each and every element of independent claim 1. Accordingly, Appellants respectfully request withdrawal of the rejection to claim 1.

Appellants submit that Kuslich discloses an implant 10, which includes a sidewall band 12. As shown below in Fig. 5, the band 12 is inserted into a small opening in the annulus 21 of an intervertebral spinal disc 23. Kuslich discloses that the band is filled to conform to the cavity in a disc or vertebrae. The band is filled and closed to prevent egress of material from the band. Col. 5, lines 6 through 12. Kuslich's band is provided around the vertebrae to support the vertebrae and encourage tissue ingrowth. See the Background of the Invention, cols. 1 through 4. The material of the band allows the ingrowth of blood vessels and fibrous and bony material. The material of the band is porous and has gaps that are tight enough to retain the small particles of fill material. See col. 8, lines 42 through 57. The band may be partially or wholly absorbable but, when filled, the band is intended to support and stabilize the spine. Col. 9, lines 15 through 61.

Clearly, Kuslich does not disclose an annular ring adapted to substantially overlie at least one annular arrangement of staples of the staple cartridge assembly, as recited in independent claim 1. Kuslich does not disclose a wound closure material dispensable from the ring, as recited in claim 1. Instead, Kuslich discloses an implant to be inserted into a small opening between two vertebrae in which the fill material is retained in the implant, as shown below in FIG. 5.



**Fig. 5**



Accordingly, in view of the foregoing amendments and remarks, Appellants respectfully submit that Kuslich fails to disclose or even suggest each and every element recited in claim 1, because Kuslich does not disclose or suggest a support structure including, *inter alia*, an annular ring configured and adapted to substantially overlies the at least one annular arrangement of staples of the staple cartridge assembly, the annular ring defining a reservoir that retains a wound closure material that is releasable therefrom, as recited in claim 1.

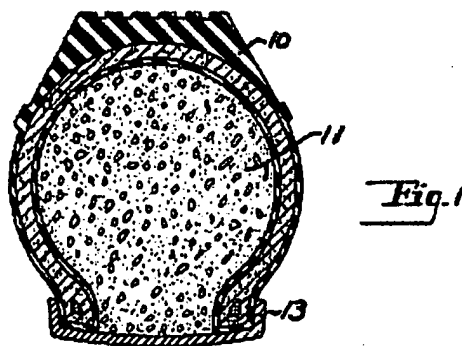
In view of the arguments presented above, Appellants respectfully submit that claim 1 is allowable under 35 U.S.C. § 102(e) over Kuslich because Kuslich fails to disclose each and every feature of claim 1.

Since claims 10, 11, 14, and 15 depend, directly or indirectly, from independent claim 1, and contain all of the features of claim 1, for the reasons presented above regarding the patentability of claim 1, Appellants respectfully submit that claims 10, 11, 14, and 15 are also patentable over Kuslich.

**C) The rejection of claim 1 under 35 U.S.C. §102(b) as being  
anticipated by U.S. Patent No. 3,022,810 to Lambe**

Claim 1 was rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 3,022,810 to Lambe. Appellants respectfully submit that claim 1 is allowable under 35 U.S.C. § 102(b) over Lambe because Lambe fails to teach each and every element of independent claim 1. Accordingly, Appellants respectfully request withdrawal of the rejection to claim 1.

Appellants submit that Lambe discloses a pneumatic tire 10 having a filling of intrinsically compressed resilient foam 11 mounted on a wheel rim 13, as shown in Fig. 1 below (See col. 4, lines 35-40). Lambe discloses a foam-filled tire that resists deflation. The foam is formed so that it cannot be released or dispensed from the tire: "it will also be observed that, by using closed-cell resilient foam having compressibilities of the same order of magnitude as air, there is no possibility that the foam will be squeezed out...". See col. 6, lines 4 through 16. Clearly, Lambe does not disclose an annular ring adapted to substantially overlies at least one annular arrangement of staples of the staple cartridge assembly, the annular ring defining a reservoir that retains a wound closure material so that it is dispensable therefrom, as recited in claim 1.



Accordingly, in view of the foregoing amendments and remarks, Appellants respectfully submit that Lambe fails to disclose or even suggest a support structure including, *inter alia*, each and every element recited in claim 1, because Lambe does not disclose or suggest an annular ring

configured and adapted to substantially overlies the at least one annular arrangement of staples of the staple cartridge assembly. Furthermore, Lambe's foam material is arranged so that it is not dispensed from the tire, to produce a tire that resists deflation.

In view of the arguments presented above, Appellants respectfully submit that claim 1 is allowable under 35 U.S.C. § 102(b) over Lambe because Lambe fails to disclose each and every feature of claim 1.

**D) The rejection of claim 23 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,909,972 to Britz**

Claim 23 was rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,909,972 to Britz. Appellants respectfully submit that claim 23 is allowable under 35 U.S.C. § 102(b) over Britz because Britz fails to teach each and every element of independent claim 23. Accordingly, Appellants respectfully request withdrawal of the rejection of claim 23.

Amended independent claim 23 recites a support structure including, *inter alia*, an annular ring configured and adapted to substantially overlies the at least one annular arrangement of staples of the staple cartridge assembly, and the annular ring having at least one removable support spoke integrally connected to and extending diametrically across the inner annular wall.

Appellants submit that Britz discloses a wheel assembly 10, which includes a rim 14, spokes 12, a tube 16 around the outside of rim 12 and a tire 18, as shown in Fig. 1 below. Britz further discloses the wheel assembly 10 can be that of a bicycle, an agricultural implement, an earth working implement, a scooter, light delivery van, motorbike or the like (*See col. 5, lines 37-42*). Clearly, Britz does not disclose an annular ring adapted to substantially overlies at least one annular arrangement of staples of the staple cartridge assembly, as recited in independent claim 23.

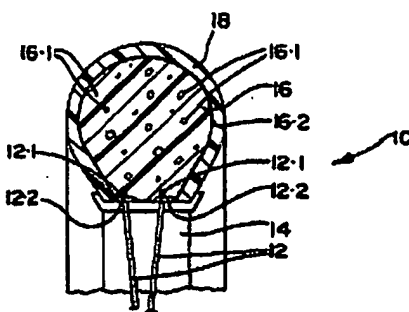


FIG 1

Accordingly, in view of the foregoing amendments and remarks, Appellants respectfully submit that Britz fails to disclose or even suggest each and every element recited in claim 1, because Britz does not disclose or suggest a support structure including, *inter alia*, an annular ring configured and adapted to substantially overlie the at least one annular arrangement of staples of the staple cartridge assembly, as recited in independent claim 23.

In view of the arguments presented above, Appellants respectfully submit that claim 23 is allowable under 35 U.S.C. § 102(b) over Britz because Britz fails to disclose each and every element of claim 23.

**E) The rejection of claim 2 under 35 U.S.C. §103(a) as being  
anticipated by Dahlke**

Claim 2 was rejected under 35 U.S.C. 103(a) as being unpatentable over Dahlke as applied to claim 1. Claim 2 depends on claim 1 and further requires that the diameter of the outer wall of the ring is configured to be substantially equal to an outer diameter of the staple cartridge. As discussed above, independent claim 1 is believed to be patentable because, among other reasons, Dahlke does not disclose a ring configured and adapted to substantially overlie an annular arrangement of staples. As claim 2 depends directly from claim 1, it is respectfully submitted that claim 2 is at least

patentable for the reasons independent claim 1 is patentable. Accordingly, withdrawal of this rejection is respectfully requested.

**F) The rejection of claims 1 and 4 under 35 U.S.C. §103(a) as  
being unpatentable over Britz in view of U.S. Patent No.  
3,022,810 to Lambe**

Claims 1 and 4 were rejected under 35 U.S.C. 103(a) as being unpatentable over Britz as applied to claim 1 above and in view of Lambe. As discussed above, independent claim 1 is believed to be patentable over Britz. Appellants respectfully submit that Lambe fails to cure the deficiencies of Britz and therefore fails to render claim 1 obvious under 35 U.S.C. 103(a). As such, Appellants respectfully submit that claim 1 is patentable under 35 U.S.C. 103(a) over Britz in view of Lambe.

As claim 4 depends directly from claim 1, it is respectfully submitted that claim 4 is at least patentable for the reasons independent claim 1 is patentable. Accordingly, withdrawal of this rejection is respectfully requested.

Appellant further submits that under Graham v. Deere, the scope and content of the prior art, the differences between the claimed invention and the prior art, and the level of ordinary skill, is the starting place for a non-obviousness analysis. See MPEP 2141.

As stated above, in rejecting claims 1 and 4 under 35 U.S.C. 103(a), the Examiner relied on the combined teachings of Britz and Lambe.

Britz discloses, as seen in FIG. 1, a wheel assembly and states: "This invention relates to wheels. It relates in particular to a method of making a solid core or tube locatable between a wheel rim and a tire fitted to the rim, to a solid core when so made, and to mould apparatus for making such a solid core." (see col. 1, lines 5 through 17). The wheel assembly includes a central hub or boss

and spokes extending radially outwardly from the hub or boss. The wheel assembly has a toroidal solid core or tube around the outside of a rim and a tire is disposed around the core so that that core is located between the tire and the rim. (see col. 5, lines 16 through 26). The wheel assembly can be used in a bicycle, van, motorbike, etc. (see col. 5, lines 37 through 42). Methods and apparatus for molding the solid core by introducing a foamable material in a mold cavity and then fitting it inside the tire are disclosed. (see col. 11, lines 22 through 49).

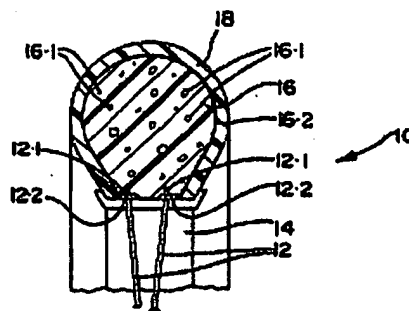


FIG 1

The Examiner asserted that Britz disclosed the invention substantially as claimed, but did not disclose a wound treatment material releasable from the reservoir. It was asserted that Lambe, which also addresses a tire, teaches a wound closure material injectable and releasable from a reservoir analogous to the reservoir of Britz.

However, Appellant submits that Lambe is directed to a deflation-proof tire and makes no mention of treating wounds and the like. (see U.S. Pat. 3,022,810, the title). As discussed in Section C of the present Appeal Brief, the foam disclosed in Lambe is not dispensable from the tire. Neither of these references, namely Britz nor Lambe, disclose a ring configured and adapted to substantially overlie an annular arrangement of staples, or a wound closure material as claimed. Applicant regards these differences between claim 1 and the cited art to be significant, patentable differences.

MPEP 2141 also states as follows:

The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that "[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR*, 550 U.S. at \_\_\_, 82 USPQ2d at 1396.

The Examiner stated that one of ordinary skill would modify Britz in view of Lambe so that the wound closure material is releasable from the reservoir and that such a modification would allow adjustment of the volume and pressure of wound closure material and air injected into the reservoir and it would allow in-situ filling of the reservoir. However, the claimed invention is not directed to a method of molding a fill material inside a tire. Appellants submit that there is simply no reason that a person of ordinary skill in the art would arrive at a support structure comprising a ring configured and adapted to substantially overlie an annular arrangement of staples and having a reservoir with a wound closure material retained therein and dispensable therefrom, upon combining the references relied upon by the Examiner.

Additionally, MPEP 2141.01(a) states as follows:

The examiner must determine what is "analogous prior art" for the purpose of analyzing the obviousness of the subject matter at issue. \*\*>"Under the correct analysis, any need or problem known in the field of endeavor at the time of the invention and addressed by the patent [or application at issue] can provide a reason for combining the elements in the manner claimed." *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_, \_\_\_, 82 USPQ2d 1385, 1397 (2007). Thus a reference in a field different from that of applicant's endeavor may be reasonably pertinent if it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his or her invention as a whole.

The problem addressed by the application is the delivery of wound closure material to tissue while deploying staples from a stapler having an annular array of staples. For example, the wound closure material can be an adhesive, a sealant or a hemostat. (See application at page 13). Since Britz and Lambe address molding a fill material inside a tire, and not the delivery of a wound closure material to tissue during surgery, they are not references that logically would have commended themselves to an inventor's attention in considering the invention as a whole.

Accordingly, the withdrawal of the rejection of claims 1 and 4 under 35 U.S.C. 103(a) as being unpatentable over Britz in view of Lambe, is respectfully requested.

**G) The rejection of claim 5 under 35 U.S.C. §103(a) as being unpatentable over Britz in view of Lambe and further in view of U.S. Patent No. 4,231,407 to James**

Claim 5 was rejected under 35 U.S.C. 103(a) as being unpatentable over Britz as applicable to claim 1 in view of Lambe as applied to claim 4, and further in view of U.S. Patent No. 4,231,407 to James. As discussed above, independent claim 1 is believed to be patentable over Britz. Appellants respectfully submit that Lambe and/or James, either alone or in combination with one another, fail to cure the deficiencies of Britz and therefore fail to render claim 1 obvious under 35 U.S.C. 103(a). As such, Appellants respectfully submit that claim 1 is patentable under 35 U.S.C. 103(a) over Britz in view of Lambe and further in view of James.

As claim 5 depends directly from claim 1, it is respectfully submitted that claim 5 is at least patentable for the reasons independent claim 1 is patentable. Accordingly, withdrawal of this rejection is respectfully requested.



Appellant further submits that under Graham v. Deere, the scope and content of the prior art, the differences between the claimed invention and the prior art, and the level of ordinary skill, is the starting place for a non-obviousness analysis. See MPEP 2141.

As stated above, in rejecting claim 5 under 35 U.S.C. 103(a), the Examiner relied on the combined teachings of Britz and Lambe and further in view of James.

Britz discloses, as seen in FIG. 1, a wheel assembly and states: "This invention relates to wheels. It relates in particular to a method of making a solid core or tube locatable between a wheel rim and a tire fitted to the rim, to a solid core when so made, and to mould apparatus for making such a solid core." (see col. 1, lines 5 through 17). The wheel assembly includes a central hub or boss and spokes extending radially outwardly from the hub or boss. The wheel assembly has a toroidal solid core or tube around the outside of a rim and a tire is disposed around the core so that that core is located between the tire and the rim. (see col. 5, lines 16 through 26). The wheel assembly can be used in a bicycle, van, motorbike, etc. (see col. 5, lines 37 through 42). Methods and apparatus for molding the solid core by introducing a foamable material in a mold cavity and then fitting it inside the tire are disclosed. (see col. 11, lines 22 through 49).

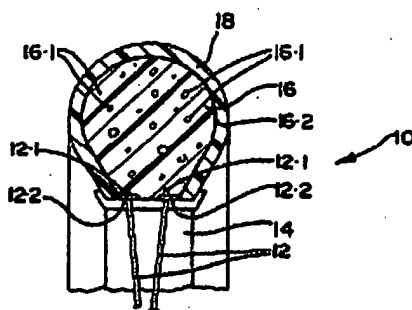


FIG 1

Lambe is directed to a deflation-proof tire and makes no mention of treating wounds and the like. (see U.S. Pat. 3,022,810, the title). As discussed in Section C of the present Appeal Brief, the foam disclosed in Lambe is not dispensable from the tire.

The Examiner asserted that Britz in view of Lambe disclosed the invention substantially as claimed, but the combination did not disclose that the hub includes a central axial opening that is configured and dimensioned to receive the shaft of the anvil assembly. It was asserted that James, which also addresses a tire, teaches a support structure with a central hub having an central axial opening to remedy the deficiencies of the combination of Britz and Lambe.

However, Appellant submits that James is directed to protective liners for tires. (see U.S. Pat. 4,231,407, the title). James fails to disclose a ring configured and adapted to substantially overlie an annular arrangement of staples, or a wound closure material as claimed. None of these references, namely Britz, Lambe nor James, discloses a ring configured and adapted to substantially overlie an annular arrangement of staples, or a wound closure material as claimed. Applicant regards these differences between claim 5 and the cited art to be significant, patentable differences.

The Examiner stated that one of ordinary skill in the art would modify Britz and Lambe in view of James so that a central axial opening in a central hub is provided and that such a modification would allow the support structure to accommodate an axle for rotation of the support structure and connection to a vehicle.

The claimed invention is directed to a support structure for use in a surgical or medical field. Accordingly, Appellants submit that vehicle and tire technology is not analogous to surgical or medical technology in that one of ordinary skill in the art of surgical and medical technology would not look to vehicle and tire technology when considering analogous art. Since the claimed invention is not directed to a device that is connected to a vehicle, Appellants submit that there is simply no

reason that a person of ordinary skill in the art would arrive at a support structure comprising a ring configured and adapted to substantially overlies an annular arrangement of staples and having a reservoir with a wound closure material retained therein and dispensable therefrom, upon combining the references relied upon by the Examiner.

The problem addressed by the application is the delivery of wound closure material to tissue while deploying staples from a stapler having an annular array of staples. For example, the wound closure material can be an adhesive, a sealant or a hemostat. (See application at page 13). Since Britz, Lambe and James address structures and methods related to a tire, and not the delivery of a wound closure material to tissue during surgery, they are not references that logically would have commended themselves to an inventor's attention in considering the invention as a whole.

Accordingly, the withdrawal of the rejection of claim 5 under 35 U.S.C. 103(a) as being unpatentable over Britz and Lambe in view of James, is respectfully requested.

**H) The rejection of claim 24 under 35 U.S.C. §103(a) as being  
unpatentable over Britz in view of James.**

Claim 24 was rejected under 35 U.S.C. 103(a) as being unpatentable over Britz as applied to claim 23 in view of James. As discussed above, independent claim 23 is believed to be patentable. As claim 24 depends directly from claim 23, it is respectfully submitted that claim 24 is at least patentable for the reasons independent claim 23 is patentable. Accordingly, withdrawal of this rejection is respectfully requested.

Appellants also respectfully submit, that none of the references cited by the Office disclose an annular ring that is configured and adapted to substantially overlies an annular arrangement of surgical staples of the staple cartridge assembly, wherein the annular ring is configured to maintain a

resulting anastomotic lumen in an open condition. Moreover, the references cited by the Office are non-analogous art because said references are not in the Appellants' field of endeavor and that said references are in no way reasonably pertinent to the particular usefulness with which the Appellants were concerned.

Appellant further submits that under Graham v. Deere, the scope and content of the prior art, the differences between the claimed invention and the prior art, and the level of ordinary skill, is the starting place for a non-obviousness analysis. See MPEP 2141.

As stated above, in rejecting claim 24 under 35 U.S.C. 103(a), the Examiner relied on the combined teachings of Britz and James.

Britz discloses, as seen in FIG. 1, a wheel assembly and states: "This invention relates to wheels. It relates in particular to a method of making a solid core or tube locatable between a wheel rim and a tire fitted to the rim, to a solid core when so made, and to mould apparatus for making such a solid core." (see col. 1, lines 5 through 17). The wheel assembly includes a central hub or boss and spokes extending radially outwardly from the hub or boss. The wheel assembly has a toroidal solid core or tube around the outside of a rim and a tire is disposed around the core so that that core is located between the tire and the rim. (see col. 5, lines 16 through 26). The wheel assembly can be used in a bicycle, van, motorbike, etc. (see col. 5, lines 37 through 42). Methods and apparatus for molding the solid core by introducing a foamable material in a mold cavity and then fitting it inside the tire are disclosed. (see col. 11, lines 22 through 49).

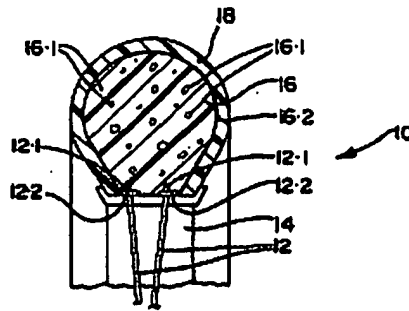


FIG 1

James is directed to protective liners for tires. (see U.S. Pat. 4,231,407, the title).

The Examiner asserted that Britz disclosed the invention substantially as claimed, but did not disclose that the hub includes a central axial opening that is configured and dimensioned to receive the shaft of the anvil assembly. It was asserted that James, which also addresses a tire, teaches a support structure with a central hub having an central axial opening to remedy the deficiencies of Britz.

As stated above in Section G of the Appeal Brief, Appellant submits that James fails to disclose a ring configured and adapted to substantially overlies an annular arrangement of staples, or a wound closure material as claimed. Neither of these references, namely Britz, nor James, discloses a ring configured and adapted to substantially overlies an annular arrangement of staples, or a wound closure material as claimed. Applicant regards the differences between claim 24 and the cited art to be significant, patentable differences.

The Examiner stated that one of ordinary skill in the art would modify Britz in view of James so that a central axial opening in a central hub is provided and that such a modification would allow the support structure to accommodate an axle for rotation of the support structure and connection to a vehicle. However, the claimed invention is not directed to a device that is connected to a vehicle. Appellants submit that there is simply no reason that a person of ordinary skill in the art would arrive at a support structure comprising a ring configured and adapted to substantially overlies an annular

arrangement of staples and having a reservoir with a wound closure material retained therein and dispensable therefrom, upon combining the references relied upon by the Examiner.

The problem addressed by the application is the delivery of wound closure material to tissue while deploying staples from a stapler having an annular array of staples. For example, the wound closure material can be an adhesive, a sealant or a hemostat. (See application at page 13). Since Britz and James address structures and methods related to a tire, and not the delivery of a wound closure material to tissue during surgery, they are not references that logically would have commended themselves to an inventor's attention in considering the invention as a whole. Applicant submits that Britz and James are non-analogous art.

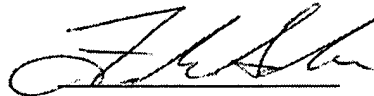
Accordingly, the withdrawal of the rejection of claim 24 under 35 U.S.C. 103(a) as being unpatentable over Britz in view of James, is respectfully requested.

**CONCLUSION**

In view of the foregoing amendments and remarks, reconsideration of the application and allowance of all pending claims is earnestly solicited.

Should the Examiner believe that a telephone interview may facilitate prosecution of this application, the Examiner is respectfully requested to telephone Appellants' undersigned representative at the number indicated below.

Respectfully submitted,



Francesco Sardone  
Reg. No. 47,918  
Attorney for Appellants

***Carter, DeLuca, Farrell & Schmidt, LLP***  
445 Broad Hollow Road – Suite 225  
Melville, New York 11747  
Tel.: 631-501-5700  
Fax: 631-501-3526  
FS/nr

**VII. APPENDIX OF CLAIMS:**

Claim 1. A support structure, for use in conjunction with a circular endoscopic stapling instrument having a staple cartridge assembly and an anvil assembly, the staple cartridge assembly having at least one annular arrangement of staple slots and staples positioned in the slots, the support structure comprising:

an annular ring configured and adapted to substantially overlies the at least one annular arrangement of staples of the staple cartridge assembly the annular ring including:

an outer annular wall having a diameter;

an inner annular wall spaced a radial distance inward of the outer annular wall and defining a space;

an upper wall interconnecting the outer annular wall and the inner annular wall; and

a lower wall spaced a distance from the upper wall and interconnecting the outer annular wall and the inner annular wall, the outer annular wall, the inner annular wall and the upper and lower walls defining an interior reservoir; and

a wound closure material retained in the reservoir and dispensable therefrom.

Claim 2. The support structure according to claim 1, wherein the diameter of the outer annular wall is configured to be substantially equal to an outer diameter of the staple cartridge assembly and wherein the diameter of the inner annular wall is configured to be radially inward of the at least one annular arrangement of staples of the staple cartridge assembly.



Claim 3. The support structure according to claim 1, wherein the annular ring has a cross-sectional profile selected from the group consisting of circular, rectilinear, ovular, triangular and arcuate.

Claim 4. The support structure according to claim 1, further comprising at least one removable support spoke integrally connected to and extending diametrically across the inner annular wall.

Claim 5. The support structure according to claim 4, wherein the anvil assembly includes an elongated shaft, and wherein the at least one removable support spoke includes a central hub having a central axial opening formed therethrough, wherein the central axial opening is configured and dimensioned to receive the shaft of the anvil assembly therethrough.

Claim 6. The support structure according to claim 1, wherein the wound closure material is at least one of an adhesive, a hemostat and a sealant.

Claim 7. The support structure according to claim 6, wherein the adhesive is selected from the group consisting of protein derived materials, albumin/glutaraldehyde materials, and cyanoacrylate-based materials.

Claim 8. The support structure according to claim 6, wherein the sealant is selected from the group consisting of fibrin based materials, collagen-based materials, synthetic polymer-based materials, synthetic polyethylene glycol-based materials, and hydrogel materials.

Claim 9. The support structure according to claim 6, wherein the hemostat is selected from the group consisting of fibrin-based materials, collagen-based materials, oxidized regenerated cellulose-based materials, gelatin-based materials, and fibrinogen-thrombin combination materials.

Claim 10. The support structure according to claim 1, wherein at least one of the annular outer wall and the annular inner wall is comprised of a rigid material.

Claim 11. The support structure according to claim 10, wherein the rigid material is selected from the group consisting of stainless steel and titanium.

Claim 12. The support structure according to claim 10, wherein the rigid material is a bioabsorbable material.

Claim 13. The support structure according to claim 1, wherein the rigid annular ring includes a plurality of interstitial spaces extending therethrough, the spaces being configured and adapted to allow the legs of the staples to pass through the spaces.

Claim 14. The support structure according to claim 1, wherein the annular ring has a plurality of cartridge orientation members adapted to orient the spaces of the annular ring to radially and circumferentially overlie the staple slots of the staple cartridge assembly.

Claim 15. The support structure according to claim 14, wherein the cartridge orientation members are a plurality of nubs extending therefrom, wherein the nubs are spaced from each other and are adapted and configured to engage complementary recesses formed in the distal end surface of the staple cartridge assembly.

Claim 23. A support structure, for use in conjunction with a circular endoscopic stapling instrument having a staple cartridge assembly and an anvil assembly, the staple cartridge assembly having at least one annular arrangement of staple slots and staples positioned in the slots, the support structure comprising:

an annular ring configured and adapted to substantially overlie the at least one annular arrangement of staples of the staple cartridge assembly, the annular ring including:

an outer annular wall having a diameter;

an inner annular wall spaced a radial distance inward of the outer annular wall and defining a space;

an upper wall interconnecting the outer annular wall and the inner annular wall; and

a lower wall spaced a distance from the upper wall and interconnecting the outer annular wall and the inner annular wall, the outer annular wall, the inner annular wall and the upper and lower walls defining an interior reservoir;

a wound closure material retained in the reservoir; and

at least one removable support spoke integrally connected to and extending diametrically across the inner annular wall.

Claim 24. The support structure according to claim 23, wherein the anvil assembly includes an elongated shaft, and wherein the at least one removable support spoke includes a central hub having a central axial opening formed therethrough, wherein the central axial opening is configured and dimensioned to receive the shaft of the anvil assembly therethrough.

**IX. EVIDENCE APPENDIX**

None.

**X. RELATED PROCEEDINGS APPENDIX**

None.